

REMARKS

Claims 4, 6-8, 10, 12 and 14-19 are pending and stand ready for further action on the merits. Claims 1-3, 5, 9, 11 and 13 have been cancelled.

Interview

Applicants note with appreciation that the Examiner has conducted a personal Interview with Applicants' representative, Garth M. Dahlen, Ph.D., Esq. at the United States Patent and Trademark Office. Also, Applicants appreciate the telephone discussion that the Examiner's Supervisor, Mr. Gary Kunz had with Dr. Dahlen on July 13, 2005 and the telephone message Mr. Kunz left with Dr. Dahlen on the evening of July 18, 2005.

Applicants are grateful to both Examiner Pryor and Mr. Kunz for their forthrightness in informing Dr. Dahlen that the claims stand rejected under 35 U.S.C. §112, first paragraph at the request of the Quality Review Board. Both Examiner Pryor and Mr. Kunz appear to be in agreement with Applicants that the rejection as stated in the outstanding Office Action is not tenable without additional evidence in support of non-enablement. Mr. Kunz suggested that Applicants file this paper so that Examiner Pryor and Mr. Kunz would then be in a better position to advance justice.

Scope of Enablement Issues

Claims 4, 6-8, 10, 12 and 14-19 are rejected under 35 U.S.C. §112, first paragraph. The PTO alleges that the specification does not enable the skilled artisan to make and/or use all of the plant activating compounds of Formula (II). The PTO asserts that the specification does enable a subgenus of the compounds of Formula (II), but the PTO does not specify which compounds are enabled. The PTO provides some guidance in stating that the subgenus should contain compounds having similar: 1) size, 2) polarity and 3) electronegativity.

Applicants respectfully traverse the rejection.

Applicants respectfully submit that the PTO's legal analysis is incorrect.

The PTO raises the question of undue experimentation in stating that "it would be a big job to determine the effect of all of the claimed compounds which would provide desired activity." However, in *Ex parte Jackson*, 217 USPQ 804 (1982), the court states:

"The test is not merely quantitative, since a considerable amount of experimentation is permissible, if [the experimentation] is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which

the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed."

What is missing is an analysis from the PTO as to why the amount of work required to practice the invention of independent claims 6, 8 and 10 would be considered undue instead of routine. It is insufficient for the PTO to merely point out that it is necessary to screen a large quantity of compounds.

In the specification, the present Inventors state that compounds of Formula (II) are useful as plant activating agents. It is improper for the PTO to make assertions against the validity of the statements made in the present specification without supporting evidence. As stated by the Federal Circuit in *In re Oetiker*, 24 USPQ2d 1443 (Fed. Cir. 1992), "[i]f the examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." (*Id.*, 24 USPQ2d at 1444).

Accordingly, the PTO has the burden of showing that the application is nonenabling (i.e., that it does not sufficiently teach how to make and use the invention). MPEP § 2164.04 instructs that a specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the

subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. As stated by the Federal Circuit:

When rejecting a claim under the enablement requirement of Section 112, the [Patent Office] bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. *In re Wright*, 999 F.2d 1557, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

Upon review of the outstanding Office Action, all that can be found are bare assertions without evidentiary support and there is no technical reasoning provided for doubting that compounds of inventive Formula (II) are useful as plant activating agents.

The analysis under 35 USC 112, first paragraph is set forth at MPEP §2164.01(a). This section lists many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure satisfies/does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In the outstanding Office Action, the PTO focuses on factor (E), the level of predictability in the art.

With regard to factor (E), *In re Angstadt*, 190 USPQ 214 (C.C.P.A. 1976) is controlling to the present fact situation. *Angstadt* is an example of when the invention involved an unpredictable chemical reaction and the application was rejected as nonenabling. In *Angstadt*, the invention related to a chemical reaction process that produced various oxidation products, including the preferred hydroperoxide product. The invention included the discovery that certain metals could be used as catalysts to provide excellent production yields of the hydroperoxides at a much faster rate. The Examiner rejected the application claims as nonenabling, in part because the disclosure did not explain how operative catalysts could be determined to perform the claimed process.

On appeal, the CCPA reversed, remarking that the requirements for enabling one of ordinary skill to make and use the invention depended, in part, on the predictability and repeatability of the invention. As stated by the CCPA, "[w]e note that many chemical processes, ... are unpredictable, ... and that the scope of enablement varies inversely with the degree of unpredictability involved." *Id.*, 190 USPQ at 218 (citing *In re Mercier*, 185 USPQ 774, 779 (C.C.P.A. 1975); *In re Fisher*, 166 USPQ 18, 24 (C.C.P.A. 1970).

The CCPA acknowledged that the claimed invention was unpredictable. Evidence of unpredictability included the fact that of the disclosed 40 examples of chemical reactions in the application, one provided no hydroperoxides at all. The CCPA also added that the specification did not disclose every catalyst that would work or every catalyst that would not work. Nevertheless, the CCPA held that even in unpredictable arts, the specification need not disclose every example or species covered by a claim:

To require such a complete disclosure would apparently necessitate a patent application or applications with "thousands" of examples or the disclosure of "thousands" of catalysts. . . . More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed. A

potential infringer could readily avoid "literal" infringement of such claims by merely finding another analogous catalyst complex which could be used in "forming hydroperoxide." *In re Angstadt*, 190 USPQ at 218.

Because the application included a list of catalysts and taught how to make and use them, the CCPA held that the experimentation required to determine which catalysts produced the asserted results was not overly burdensome. Therefore, the CCPA held the application to be enabling under Section 112, first paragraph.

Thus, parallels between *Angstadt* and the present case are numerous. Certainly there is some unpredictability in determining the activity of plant activating agents, but determining the activity of the instant plant activating agents would not be overly burdensome. It is clear that the genus of compounds of claims 6, 8 and 10 have sufficiently similar 1) size, 2) polarity and 3) electronegativity to the large variety of compounds tested in the present specification (see the tables on pages 24-40 of the specification), such that the skilled artisan could use the present invention without undue burden.

When applying the rationale set forth in *Angstadt* to the instant case and the weighing each of factors (A) through (H), even though there is a certain level of unpredictability in the field,

the skilled artisan would not have an undue burden to make and/or use all of the compounds of Formula (II) as plant activating agents.

Lastly, the PTO asserts that small changes in the functional feature of the compound could result in a "drastic change in activity and such a change can also result in an opposite effect or activity." Thus, it appears that **Judicial Notice** of this fact has been taken in view of the lack of evidentiary support for the assertion.

MPEP 2144.03 sets forth the very limited situations when **Judicial Notice** is proper.

[T]he notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute"... It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. (Emphasis in original).

Applicants respectfully traverse the assertion that a small change in the functional feature of a compound useful as a plant activating agent could result in a "drastic change in activity and such a change can also result in an opposite effect or activity." Applicants' position is supported by the experimental evidence in

the specification, wherein a large number of compounds (relative to the small genus of compounds claimed) differing in structure are shown to have activity as plant activating agents.

If the PTO is relying on art based information to support the assertion that small changes in structure of plant activating compounds results in a drastic change in activity, Applicants request that this art based information be made of record. If the assertion is based on personal knowledge, Applicants request an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2).

Based on the foregoing, it is clear that the present invention meets the enablement requirement of 35 USC 112, first paragraph, and withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above comments, Applicants respectfully submit that the claims are in condition for allowance. A Notice to such effect is earnestly solicited.

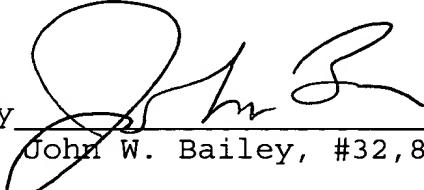
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact **Garth M. Dahlen, Ph.D., Esq.** (Reg. No. 43,575) at the telephone number of the undersigned below, to conduct an

interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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